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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,242	05/25/2001	Anthony L. Fitzhugh	17363-38	3958

7590

06/18/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,242

Applicant(s)

FITZHUGH ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 19, 20, 22, 23 and 25-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 29-32 is/are allowed.

- 6) ☒ Claim(s) 15-17, 19, 20, 22, 23 and 25-28 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other:

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DETAILED ACTION

Examiner acknowledges receipt of formal drawings filed 02/21/03, IDS, request for continued examination under 37 CFR 1.114 and petition to withdraw from issue, all filed 03/24/03 and transmittal of IDS information (correcting the transmittal information of 03/24/03) filed 05/01/03.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on 03/24/03 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claim 15 is rejected under 35 U.S.C. 102(a) as being anticipated by Tedeschi et al. (EP 0 992 252).

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Tedeschi discloses medical devices such as guide wires, stents and catheters (column 9, lines 53-55) that are coated with lubricious coating (column 9, lines 34-36). The coating composition comprises a mixture of polyisocyanate, an amine and/or hydroxyl donor, polymer selected from polyethylene oxide, polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene glycol and polyacrylic acid and a solvent (column 4, line 55 to column 5 line 6). The coating composition is capable of releasing drugs and an example of active agent that can be released is nitric oxide (column 5, lines 7-27, column 6, lines 44 to column 9 line 4). Instant claim 15 recites three-dimensional matrix and this property is inherent to the matrix of the prior art. Thus Tedeschi meets the limitations of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 16, 17, 19, 20, 22, 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tedeschi et al. (EP 0 992 252).

Tedeschi teaches the medical device of the instant application and in column 3, lines 40-45 specifically discloses that NO is known to be used to prevent and/or treat complications such as restenosis and thrombus formation when delivered to the treatment site that come in contact with synthetic medical devices.

Regarding claim 16 and 17, Tedeschi teaches that the polymer can be acrylic polymer derived and the instant application has not demonstrated that acrylic polymer that is a hydrogel

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provides some unusual results to the polymer coated medical device. Regarding claim 19, it would be obvious to modify the amount of NO releasing precursor in several layers with the expectation of optimizing the amount of NO oxide released to the site of treatment.

While Tedeschi teaches coated medical device that is capable of releasing NO active agent to the site of treatment, Tedeschi fails to teach a method of treating or inhibiting restenosis with the NO releasing medical device, and the instant method provides the medical device for delivery to the treatment area. Since it is known that NO is used to prevent and/or treat complications such as restenosis and thrombus formation when delivered to a treatment site that come in contact with synthetic medical devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the NO containing medical device of Tedeschi. One having ordinary skill in the art would have been motivated to introduce the coated device containing the NO releasing precursor to a site in need of treatment for restenosis with the expectation that the NO will be released from the device for treating restenosis at the affected site.

6. Claims 29-32 are allowable because the prior art does not teach a method of coating a medical device with polyethylenimine according to the steps of claim 29.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center
June 14, 2003

A handwritten signature in black ink, appearing to read "Blessing Fubara", written over the printed name.